REMARKS

Reconsideration and withdrawal of the rejection and the allowance of all claims now pending in the above-identified patent application (*i.e.*, Claims 33-35, 37, 39 and 41-58) are respectfully requested in view of the foregoing amendments and the following remarks.

Claim Rejections

Claim 33 is the only pending independent claim that has not yet been allowed or indicated as being allowable over the prior art. The Examiner rejected claim 33 under 35 U.S.C. 102(b) and (e) as being anticipated by U.S. Patent 5,755,226 (*Carim*) and U.S. Patent 6,078,833 (*Hueber*), respectively, and also under 35 U.S.C. 103(a) as being unpatentable over either U.S. Patent No. 4,407,290 (*Wilber*) or U.S. Patent 6,064,986 (*Rosenthal*) in view of *Carim*.

At the outset, it should be recalled that the present invention provides an apparatus and related method for a measurement of at least one analyte in the blood of a patient, *e.g.*, the measurement of a patient's blood glucose level, hemoglobin index or blood oxygen saturation level. The claimed apparatus utilizes a plurality of transmitting fibers positioned for transmitting broadband light to blood of the patient, a fiber optic bundle leading light that is transmitted through, or reflected by, the blood to a detection arrangement, and a light detection arrangement that separates the received light into spectral components and computes a measurement of the analyte of interest as a function of the

strength of each spectral component.

Claim 33 recites two features which, together, are lacking not only in Carim, but also in any of the hypothetical combinations of Carim with the devices disclosed in the secondary references Hueber, Wilber and Rosenthal. These limitations are:

1) use of the non-pulsatile component of the light transmitted into the patient's body; and,

2) use of a broadband light not only for transmission, but also in the reception and processing stage.

Use of Non-Pulsatile Component

Means for measuring various blood analytes have conventionally relied upon utilizing the pulsatile component of the light transmitted through a particular body part of the patient being examined. Such pulsatile techniques of analysis have the clear disadvantage that the pulsatile component of the light signal, whether transmitted or reflected, is less than 2% of the total signal. Consequently, prior art devices which use only the pulsatile component are much less sensitive, and much more vulnerable, to patient movement, which can cause interference, and which can frequently be in the order of a few hundred times the relevant signal.

Further, the pulsatile signal specifically identifies arterial blood. While this is advantageous when considering pulmonary circulation of the patient, it provides no information on the patient's systemic circulation. Additionally, pulsatile techniques are typi-

cally limited to use on body extremities, such as fingers, ear lobes, or the ball of the foot of babies or neonates. As will be explained in greater detail hereinafter, nowhere in the prior art is such a novel and efficient apparatus and method for a measurement of at least one blood analyte, utilizing a non-pulsatile element of the patient's blood, either disclosed or suggested.

The Examiner contends that *Wilber* teaches an apparatus and method for determining several chemical analytes, including oxygen saturation, glucose, hematocrit and carbon dioxide in blood. Both Wilber and Carim appear limited to devices and methods for measuring blood constituents that utilize a pulsatile component of the patient's blood for measurement of various blood analytes, rather than a non-pulsatile, as per Applicants' claimed invention. Wilber teaches that the suggested blood-containing tissue sample intended for analysis is, for example, an ear lobe (Wilber, Abstract at lines 9-13; Col. 3, lines 66-67), which is typical for pulsatile techniques (*see*, Applicants' Specification at Page 5, lines 6-11). Wilber removes the non-pulsatile (DC) information through a process of normalization, as explained in Col. 4, lines 19-33:

> The pulse train output from converter 25 is coupled through test unit 26 to normalization unit 52 of normalizing section 27 where the signal representative of the light received from each emitter is scaled so that the DC components of each are normalized to a predetermined reference level .... The normalization circuit functions to scale both the AC and DC components of each signal so that the DC (average) component is made equal to a known, preset level.

Likewise, Carim expressly states that "[t]he present invention provides a repeatable, quantifiable method of prediction that evaluates the waveform for peaks,

valleys, DC averages, and pulsatile averages." (Carim, Col. 6, lines 43-47).

Consequently, combining the teachings of Wilber and Carim, in the manner suggested by the Examiner, would, at best, yield an apparatus and method that measured blood constituents in a non-invasive manner, which relied upon measurement of a pulsatile component of the patient's blood, contrary to that claimed by Applicants.

Broadband Transmission *and* Reception

Claim 33 recites: "a light-transmission arrangement including a plurality of transmitting fibers positioned for simultaneously transmitting the multiple wavelengths of the broadband light from the source to the blood." In short, the invention transmits broadband light from the source. Claim 33 also recites an optical fiber arrangement having a plurality of light detector fibers for leading multi-wavelength light, *in spectrally unseparated form*, transmitted through, or reflected from, the blood" and "a light detection arrangement receiving the multi-wavelength light in its *spectrally unseparated form* from the optical fiber arrangement, for spectrally decomposing the received light, and for determining amplitudes of selected wavelengths of the decomposed light." In short, the Applicants' invention is able to use broadband light at both "ends." One way to achieve this is though the use of the spectrophotometer's diffraction grating described in the Example of the invention described at Page 8 of Applicant's Specification and, particularly in the first paragraph at Page 9 of the textual disclosure.

In contrast, Carim mechanically separates the bundle of optical fibers in his

"collecting bundle 330" into a plurality of "channels" 332, with one sub-bundle (channel) for each wavelength of interest. *See, e.g.*, Carim's FIG. 2 and Col. 13, lines 35-62. This choice has detrimental consequences for Carim's system, not only in terms of sensitivity, but also in terms of complexity. By way of a very simple example, assume that 100 units of light energy are being conveyed in the Carim collecting bundle 330, that this bundle is separated into ten channels 332, each carrying $1/10^{th}$ the energy of the whole bundle, and that the strength of each spectral component is roughly 10% of the whole. For each wavelength of interest, the amount of energy making it through each filter 120a, ..., 120n and applied to each A/D converter will therefore be 100 / 10 * 0.10 = 1.0 unit.

Consider now the relationship but in the configuration defined in the Applicants' independent Claim 33, as amended: Since the entire amount of broadband light received is applied to the light detection arrangement (such as the diffraction grating), each A/D converter (found in all modern spectrophotometers) will be 100 * 0.1 = 10 units.

Applicants' claimed configuration also has the advantage of much greater simplicity, with no need to separate and separately route groups of fibers in the reception bundle and no need for the fresnel lens collimators 334 and interference filters 336.

It would not be obvious to combine Carim and either Wilber or Hueber, because Carim teaches the "reverse" of the others: Were one to use Wilber's multiple LEDs or Hueber's multiple light sources 20, 21, 23 and 25 for transmission in Carim, then the single wavelengths of the LEDs/sources would be mixed in Carim's collecting bundle and would eliminate the entire reason for the separate light sources in the first place. Alterna-

tively, it would eliminate the need for Carim's separation of the collection bundle into different fiber groups (channels), since the wavelengths would already have been separated upon transmission.

Novelty and Non-Obviousness of the Invention

Claim 33 now includes limitations that define the invention to have a technically advantageous configuration for measurement of at least one blood analyte using the non-pulsatile component, which is not found in Carim or Hueber, and which therefore fail to anticipate the invention. Moreover, Applicants' use of broadband light, both for transmission and pre-processing reception, is not found in any of the cited references. It is, therefore, respectfully submitted that no combination of the references would be possible without completely departing from the teachings of at least one of the references in the combination of references applied by the Examiner and; consequently, Applicants' invention, as recited in independent Claim 33, is contended to be nonobvious over any combination of the references of record.

Allowed and Allowable Claims

Applicants wish to thank the Examiner for his allowance of independent Claims 55 and 56, and his indication of the allowability of the subject matter of dependent Claims 38 and 40, as part of the first Office Action issued for the instant patent application.

By the present amendments, Applicants have cancelled dependent Claims 38 and

40, and have written the subject matter thereof as new independent Claims 57 and 58, respectively. In light of the Examiner's indicated allowability of the subject matter of prior Claims 38 and 40, it is respectfully submitted that new Claims 57 and 58 are in condition for allowance at this time.

The claims have also been amended for improved form and clarity, as appropriate.

Additional Claims

There now being a total of five (5) independent claims pending in the above-identified patent application (*i.e.*, Claims 33 and 55-58), Applicants hereby remit the additional claims fee of $172.00 (in addition to the requisite extension fee) to cover the pendency of two independent claims beyond the three independent claims covered by the U.S. National Fee paid upon entry of this §371 application into the U.S. National Phase.

Other Cited References

Concerning, finally, the remaining references made of record by the Examiner, but not applied in any rejection of Applicants' claims, such additional art references have been carefully considered, but are not believed to adversely affect the patentability of the present invention, as now claimed.

Conclusion

In light of the foregoing, it is respectfully contended that all claims now pending in the above-identified patent application (*i.e.*, Claims 33-35, 37, 39 and 41-58) recite a

novel and efficient apparatus and method for a non-invasive measurement of at least one blood analyte utilizing a non-pulsatile element of the patient's blood, which is patentably distinguishable over the prior art. Accordingly, withdrawal of the outstanding rejection and the allowance of all claims now pending are respectfully requested and earnestly solicited.

Respectfully submitted,

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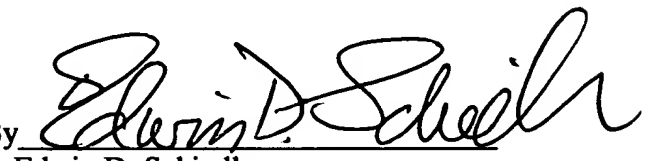
By 
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July 26, 2004

Enc.: 1. Petition for Two-Month Extension of Time; and,

2. Check for $592.00 (Extension Fee ($420) + Additional Claims Fee ($172))

The Commissioner is hereby authorized to charge the Deposit Account of Applicants' Attorney, Account No. 19-0450, for any additional fees which may be due in connection with the prosecution of the present application, but which have not otherwise been provided for.